UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,763	10/24/2003	Paul J. DeGroot	P-8237.00	2173

27581 7590 04/06/2006

MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER	
JOHNSON, SHEVON ELIZABETH	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,763	DEGROOT ET AL.	
	Examiner	Art Unit	
	Shevon E. Johnson	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12,15-18 and 21-32* is/are rejected.

7)☒ Claim(s) *6,13,14,19 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/04 and 5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Objections

Claim 32 is objected to because of the following informalities: In line 1, "a method" should be changed to "a medium." Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 15-18, 21 and 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Winstrom (U.S. Patent No. 4,800,883), as cited by applicant.

In regards to claims 15-18, Winstrom discloses a method of delivering at least one complex defibrillation waveform to a portion of cardiac tissue, comprising the steps: confirming the presence of a cardiac arrhythmia terminable by delivery of a defibrillation waveform; generating at least one pulse-modulated slow-rise defibrillation waveform portion until said slow-rise defibrillation waveform portion reaches a predetermined amplitude; allowing the amplitude of the defibrillation waveform to decay exponentially for either a predefined period of time or until a predetermined voltage threshold is reached; truncating said defibrillation waveform; providing said defibrillation waveform to a portion of cardiac tissue; after the truncating step, generating a second defibrillation waveform of opposite polarity to said at least one pulse-modulated slow-rise defibrillation waveform; providing said second defibrillation waveform to the portion of cardiac tissue; wherein said second defibrillation waveform comprises an initial slow-rise defibrillation waveform portion; wherein said initial slow-rise defibrillation waveform portion is followed by an exponentially decaying portion, and said decaying portion if followed by a truncated portion (col. 14, line 51 – col. 17, line 37; fig. 8c).

In regards to claim 21, Winstrom discloses a method wherein a total duration of said defibrillation waveform includes a range of approximately 13 ms to approximately 28 ms (col. 14, line 51 – col. 17, line 37; fig. 8c).

In regards to claims 24-32, Winstrom discloses a controller 9 that is inherently capable of storing executable instructions for performing a method of delivering at least one complex defibrillation waveform to a portion of cardiac tissue as claimed (col. 4, lines 5-42; fig. 1).

3. Claims 15 and 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiss (U.S. Patent No. 5,184,616), as cited by applicant.

In regards to claim 15, Weiss discloses a method of delivering at least one complex defibrillation waveform to a portion of cardiac tissue, comprising the steps: confirming the presence of a cardiac arrhythmia terminable by delivery of a defibrillation waveform; generating at least one pulse-modulated slow-rise defibrillation waveform portion until said slow-rise defibrillation waveform portion reaches a predetermined amplitude; allowing the amplitude of the defibrillation waveform to decay exponentially for either a predefined period of time or until a predetermined voltage threshold is reached; truncating said defibrillation waveform; providing said defibrillation waveform to a portion of cardiac tissue (col. 15, lines 11-25; fig. 8).

In regards to claims 24-32, Weiss discloses a processor 16 that is inherently capable of storing executable instructions for performing a method of delivering at least one complex defibrillation waveform to a portion of cardiac tissue as claimed (col. 11, lines 58-65; col. 12, lines 49-67; col. 15, lines 11-25; figs. 1, 4 and 8).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5, 7-9, 15 and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brink (U.S. Patent No. 5,725,560), in view of Weiss '616 and Winstrom '883, as cited by the applicant.

In regards to claims 1-5 and 7-8, Brink, Weiss and Winstrom discloses a system for generating a slow-rise waveform to deliver defibrillation energy to terminate a cardiac fibrillation condition, the system comprising (for example: see Brink, fig. 4): means for generating a slow-rise waveform to an predetermined amplitude modulator (converter) 72; means for converting the slow-rise waveform to an exponential decaying waveform for a predetermined period of time; and means for truncating said slow-rise waveform upon the expiration of the predetermined period of time. For details of the multiphasic generators and components as claimed refer to: Brink 560': col. 5, line 26 – col. 7, line 3; fig. 4; Weiss '616: col. 14, line 41 – col. 15, line 25; figs. 7 and 8; Winstrom '883: col. 12, line 10 – col. 13, line 30; figs. 1 and 5.

In regards to claim 9, Weiss discloses a system comprising at least pair of defibrillation electrode 19A and 19B (col. 12, lines 64-67; fig. 4) assemblies electrically coupled to the system at a proximal end and electrically coupled to a portion of cardiac tissue near a distal end portion and wherein said pair of assemblies includes at least one of the following: a percutaneous electrode, a subcutaneous electrode, an epicardial electrode, an endocardial electrode, a pericardial electrode, a transcutaneous electrode, a surface electrode, a canister electrode, a coil electrode, a ring electrode (col. 16, line 42 – col. 17, line 32).

In regards to claim 15, Brink discloses a method of delivering at least one complex defibrillation waveform to a portion of cardiac tissue wherein the method allows the user to create a new waveform (col. 3, line 41 – col. 4, line 16; figs. 5A-8).

One having ordinary skill in the art would appreciate that Brink, Winstrom and Weiss could be combined since they both teach multiphasic defibrillation pulse waveforms, and thus the references are

analogous art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to create a slow-rise or ramp-type exponential decay waveform as taught by Winstrom (fig. 8c) and Weiss (128, 137; fig. 8).

In regards to claim 22, Brink discloses a method wherein said pulse-modulated slow-rise waveform is generated by a high speed, power switching converter (col. 2, line 11 - col. 3, line 28).

In regards to claim 23, Brink discloses wherein the slow-rise defibrillation waveform includes one of a voltage-controlled waveform and a current-controlled waveform (col. 2, line 35-37).

In regards to claims 24-32, Brink discloses a controller 31 for executing instructions and a memory 36 for storing executable instructions for performing a method of delivering at least one complex defibrillation waveform to a portion of cardiac tissue (col. 2, lines 51 – col. 3, line 28).

6. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brink '560 and Weiss '616 in view of Brewer (U.S. Patent No. 5,991,658), as cited by the applicant.

In regards to claims 10-12, Brink and Weiss disclose the system substantially as claimed except wherein various waveforms include a characteristic tilt of between approximately 50% and 75%. However, Brewer teaches systems wherein various waveforms includes a characteristic tilt of between approximately 50% and 75% (col. 2, lines 1-33; col. 12, line 60 - col. 13, line 18; tables IA-IID).

Lacking any criticality, it would have been obvious to one of ordinary skill to have arbitrarily selected a waveform with a tilt of between 50%-70% in view of the teachings of Brewer since waveforms used by all references are used to defibrillate a patient's heart.

Allowable Subject Matter

7. Claims 6, 13, 14, 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shevon Johnson
Art Unit 3766

Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766